

DEFENDANT'S EXHIBIT

CVS-MDL-01104

# **CVS Pharmacy® DEA & Pharmacy Regulatory Training #800680**

## ***Self-Paced Guide For Pharmacists***

September 2019

Confidential

CVS-FLAG-000192956

CVS-MDL-01104.00001

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## Introduction

This guide will teach you policies and detailed procedures around DEA regulatory visits, ordering and receiving and dispensing controlled substances, as well as, recordkeeping and reporting requirements.





### Objectives

At the conclusion of this training you will be able to complete the following in accordance with CVS Health Policy and DEA regulations:

- Determine validity of each prescription
- Identify forged and altered prescriptions
- Report forged or altered prescriptions
- Dispense controlled substances
- Record and fill prescriptions for controlled substances
- Identify diversion attempts
- Report controlled substance theft and loss
- Order & receive controlled substances
- Respond to a DEA visit

### Using this Guide

The following icons are used to draw attention to the following:

	Best Practices
	RxConnect system prompts to help with the process
	CVS Health Policy
	Where to find the resource on RxNet

*Continued on next page*

## Introduction, Continued

### Supporting Resources

#### RxNet:

Spark on the RxNet page has valuable resources. This training will note specific instances where you will benefit from using job aids and reviewing policies on RxNet.

Refer to the **Policy and Procedure** tab and the **Legal & Regulatory** link circled in red below to access all relevant policies and procedures related to DEA regulations.

**CVS pharmacy RxNet**

**Legal and Regulatory**  
Last Updated July 2017

To find a topic on this page, push control and the 'F' key.

**Emergency Response**

**Policy and Procedure**

**Who to Call**

**By State**

State References  
State Specific PMP

**Clinical**

Clinical Homepage  
Clinical References  
Compounding Corner  
Immunization Programs  
iPledge | REMS  
Naloxone Support  
Patient Safety

**Compliance**

Confidential Waste  
HIPAA & Privacy  
**Legal and Regulatory**  
Loss Prevention

**Inventory and Merch**

AIMRx Inventory  
CFRx Inventory  
Marketing  
Merchandising  
Non-Saleable Returns  
Waiting Bin

**Ethics Line**  
[Ethics Line Poster](#)  
[EthicsPoint](#)

**Controlled Substances / Recordkeeping**

[Controlled Substance Inventory](#)  
[Controlled Substance Perpetual Inventory Resource Center](#)  
[Controlled Substance Resource Page](#)  
[Daily Drug Count Form](#)  
[Destruction of Expired Records Job Aid](#)  
[Document Retention Schedule](#)  
[Managing CILs and CIL-CVs Job Aid](#)  
[MethCheck](#)  
[PSE Certificate Reprinting](#)  
[PSE Certificate Reprinting Instructions](#)  
[Regulatory Records Box](#)  
[Suboxone](#)

**DEA**

[DEA 222 Process](#)  
[DEA Field Divisions](#)  
[DEA Controlled Drug Loss](#)  
[DEA Registration Validation Login](#)  
[DEA Website](#)  
[Prescriber Failure to Provide Hard Copy Prescription Fax Form](#)

### Key Contacts Ethics Line

Instances of non-compliance can be reported through the CVS Health Ethics Line:

<b>Confidential phone</b>	1-877-CVS-2040 (1-877-287-2040)
<b>Confidential email address</b>	Ethics.BusinessConduct@cvs.com
<b>Confidential fax</b>	(847) 559-3835
<b>Confidential mailing address</b>	Chief Compliance Officer CVS Health One CVS Drive Woonsocket, RI 02895

## Regulations and Compliance

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### Company Policies

All Pharmacy staff members should be familiar with the controlled substance prescription policies below.



- **Federal Regulations and CVS Guidelines for Controlled Substances (ROPP-047561).**
- **Guidelines for Dispensing Controlled Substances (ROPP-0061).**

Policy and Procedure → Controlled Substances & Recordkeeping



Corresponding responsibility applies to the dispensing of any controlled substance.

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### Penalties for Violations

**Knowingly dispensing a controlled substance ordered by an invalid prescription is illegal.** This includes prescriptions that:

- Are not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.
- Do not meet the technical requirements for a controlled substance prescription (signature, date, DEA number, etc.)
- Violate limitations on oral, facsimile, or electronic prescribing.
- Appear to have been altered, forged, or copied.



Failing to follow state or federal laws and regulations can result in serious consequences for the company and our colleagues. These include:

- Criminal penalties
  - Civil monetary fines
  - Administrative sanctions
  - Suspension or revocation of a Pharmacy's DEA registration or Pharmacy license or a Pharmacist's license.
  - Termination of employment
  - Prosecution by the DEA for knowingly and intentionally distributing controlled substances.
-

## Validating Prescriptions

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Before filling a prescription, Pharmacy colleagues must be satisfied that the prescription meets all valid requirements, and is received in a polite and accommodating manner.

**Defining a Valid  
Controlled  
Substance  
Prescription**

Only the Pharmacist can determine whether a controlled substance prescription is valid and can be dispensed. **BOTH** the following requirements must be met:

1. The prescription contains all required information and meets all federal and state requirements.

**AND**

2. The prescription was issued for a legitimate medical purpose by a prescriber acting in the usual course of their professional practice.

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**Validating Prescriptions, Continued****New  
Prescriptions****Prescriptions must have required minimum elements.**

After validating customer information in RxConnect, certain (minimum) data elements must be present to accurately and safely process prescriptions in compliance with applicable regulations. Depending on how prescriptions are received by the Pharmacy and if the drug is classified as a controlled substance, the requirements may vary.

Refer to the table below for the *minimum elements required* for each prescription type. **Additional federal or state regulation required elements** (e.g. tamper evident forms/features, prescriber's state license number or designation, supervising practitioner, etc.) **must also be present.**

	Written Prescription	Prescriber Phone-in	Prescriber Fax	Prescriber Electronic
<b>Patient Information</b>				
Patient's Full Name	ALL	ALL	ALL	ALL
Patient's Address	ALL	Controls	Controls	ALL
Patient's Date of Birth	ALL	ALL	ALL	ALL
<b>Prescription Information</b>				
Date of issuance / written	ALL	ALL	ALL	ALL
Drug name and dosage form	ALL	ALL	ALL	ALL
Drug strength (if applicable)	ALL	ALL	ALL	ALL
Quantity prescribed	ALL	ALL	ALL	ALL
Directions for use	ALL	ALL	ALL	ALL
<b>Prescriber Information</b>				
Prescriber's name*	ALL	ALL	ALL	ALL
Prescriber's address	Controls	Controls	ALL	ALL
Prescriber's phone number	ALL	ALL	ALL	ALL
Prescriber's DEA #	Controls	Controls	Controls	Controls
Prescriber's signature	ALL	N/A	ALL	N/A

\* If a state allows multiple Prescriber names printed on a prescription blank, the Prescriber issuing the prescription must be clearly indicated in the manner required by the state (E.g. check mark, circling, etc.)

“ALL” indicates this element is required on each prescription, regardless of the DEA schedule of the drug.

“Controls” indicates this element is required only on prescriptions issued for drugs in DEA schedules II, III, IV, and V.

**State Regulations**

It is the responsibility of each Pharmacy Team Member to understand their state's specific requirements for accepting different types of prescriptions (written, oral, fax, telephone, electronic, etc.)



**RxNet → Policy and Procedure tab → Accepting Prescriptions → Accepting Prescriptions Policy (ROPP-0010)**

*Continued on next page*

## Validating Prescriptions, Continued

### Oral Prescriptions

Document Oral prescriptions from prescribers on an authorized CVS Pharmacy Oral Prescription pad. Refer to the **Store Supply Order Guide on RxNet** to order the appropriate pad for your state.

Write all necessary elements legibly in indelible ink. In addition to minimum elements required, also note the following:

- Date and time received
- Initials of the CVS Pharmacy colleague receiving the prescription.
- Check mark indicating the prescription was retrieved from voicemail (if applicable).
- Necessity to dispense the brand name drug or permission to substitute an appropriate generic equivalent, as appropriate, and in the manner required by your State's regulation.
- Check mark indicating the prescription was read back or re-played must be noted.

**Note:** Do not dispense CII's with an oral prescription except in emergencies. The processes around receiving a follow-up written script are detailed in the Schedule II Prescription Requirements section of this training.

### Required Information

Below is the required information that must be present on a controlled substance prescription:

The diagram shows a prescription pad with the following fields and callouts:

- 1**: Patient's full name, address, and date issued.
- 2**: Prescriber's full name, address, and DEA Registration number.
- 3**: Drug name, strength, dosage form, quantity, and directions.
- 4**: Number of authorized refills, if any.
- 5**: Signature of the prescriber.
- 6**: Verification of the prescription is written on a tamper-proof Rx blank.

Other fields on the pad include: Lic. #, Name, Address, CITY, STATE, ZIP, DEA #, Name, Address, Date, MT, Refill NR. 1 2 3 4 5, Void After, Substitution Permitted, and a note: "In order for a brand name product to be dispensed, the prescriber must: handwrite 'Brand Necessary' or 'Brand Medically Necessary' in the space below."

**Note:** The prescription must be written on a tamper proof Rx pad, where required by state law. All **Medicaid** prescriptions must be written on a tamper proof Rx Pad.

- 1 – Patient's full name, address and the date issued.
- 2 – Prescriber's full name, address and DEA Registration number.
- 3 – Drug name, strength, dosage form, quantity and directions.
- 4 – Number of authorized refills, if any
- 5 – Signature of the prescriber
- 6 – You must also verify the prescription is written on a tamper proof Rx blank, where required.

**Note:** State law may require additional elements.

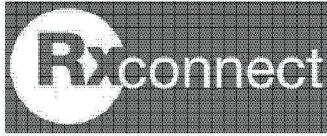


### Review tamper proof features

RxNet → Compliance → Legal and Regulatory → Third Party → Tamper Resistant

*Continued on next page*



**Validating Prescriptions, Continued****Patient Level  
Alert Message**

An RxConnect enhancement called the Patient Level Alert (PLA) message now displays at Data Entry and Data Entry Verification when a patient's profile has been identified as being associated with prescription forgery incidents.

Review the letters in the graphic below that coincide with the information below:

- A) The Pharmacy Team Member must review the PLA in its entirety prior to processing a prescription.

**Note:** Review non-controls with the same scrutiny as controls. Often times, individuals try to pass a forged non-control prior to filling a control or in conjunction with a control.

- B) Pharmacists will be required to select "Bypass and Fill" or "Do Not Fill," provide a detailed reasoning behind their decision, and enter their credentials in order to proceed.

 A screenshot of a software interface titled "Patient Alert Message". The interface is divided into several sections. On the top right, there is a box containing patient information: "Patient Name: DOE, JOHN", "DOB: 04/24/1982", and "Phone: (555) 555-5555". On the left, there is a section titled "Patient Prescription Forgery Warning" with a large letter "A" next to it. Below this, there is a "Data Entry" section with text: "Inform Patient: I need to review the prescription with you before filling. Inform RxH: Confirmed Previous Prescription Forgery. Verify all prescriptions with Prescriber, using RxH phone number first." Below that, there is a "QV: If a prescription is identified as forged, follow the Fraudulent Prescription Protocol on RxNet and alert patient." At the bottom left, there are two numbered sections: "1. Fill Option:" and "2. Comments:". To the right of these, there is a box with a large letter "B" and a "Select one of the following:" dropdown menu with options "1 - Bypass and fill" and "2 - Do not fill".

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## Validating Prescriptions, Continued

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### Lock-in Programs

When you first receive a prescription, ensure it is not part of a “lock-in program” used by some insurances to monitor the prescription activity of certain patients.

Lock-in programs may:

- Require patients to fill prescriptions in one designated lock-in Pharmacy.
- Prohibit other pharmacies from filling prescriptions outside of the lock-in Pharmacy.

Pharmacy teams should be cautious of patients attempting to evade lock-in requirements by filling prescriptions for cash or other means of payment. Overall, lock-in programs may differ by state and by insurance; it is your responsibility to ensure you are abiding by the guidelines of the insurance company and the state.

#### Your Role:

If the Pharmacy is notified of a lock-in patient, add a forced note into each patient’s profile and review the patient information and expectations of the program with all Pharmacy team members:

- Ensure that within your Pharmacy, you do not fill prescriptions for patients who are locked into another Pharmacy.
- At data entry and verification, check forced patient notes.

If the patient presents a legitimate need to fill outside of the lock-in Pharmacy, contact the payer for approval and document via a forced note in the patient’s profile. For more information, please refer to Guidelines for Dispensing Controlled Substances Policy (ROPP-0061)



**Some states have unique requirements around lock-in programs and you should be familiar with the requirements in your state.**

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### Contacting Prescribers for Verification

If information/clarification is needed for a prescription, only the Pharmacist (unless specified by the individual state law and/or Board of Pharmacy regulations) is authorized to contact the prescriber. The conversation with the prescriber’s office must be documented on the actual prescription and/or in RxConnect:

- Prescription clarifications (missing patient, prescriber, or drug information), write the information legibly on the hardcopy prescription, document the name of the person spoken to, and the date and time of the conversation.
- Document clinical questions concerning the patient and/or prescription on the hardcopy prescription or in RxConnect via the patient notes functionality.



Best practices are to **always** document in RxConnect to ensure easy note retrieval after hardcopy has been filed for long-term storage.

- State laws can restrict the types of missing information that can be added to a controlled substance prescription. In these instances, a new prescription may be required.
- Even if the prescriber indicates that the prescription should be filled as written, Pharmacists must still use their professional judgment to determine whether the prescription was issued for a legitimate medical purpose and in the usual course of professional practice.

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## Validating Prescriptions, Continued

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### Accessing and Maintaining Prescriber Records

Maintaining accurate prescriber data in RxConnect is a responsibility of all Pharmacy colleagues. Federal and state authorities have increased regulatory scrutiny around accurate prescriber data and pharmacies are expected to maintain compliance. Failure to do so can result in reporting incorrect information to your state's PDMP, which could subject CVS Health to state and federal penalties.

Pharmacists need to ensure that the correct prescriber is chosen in RxConnect, not only for controlled substances, but also in all instances. Many prescribers have multiple offices, making the correct prescriber selection challenging. By using refined searches, especially the telephone number and DEA number, Pharmacy colleagues are able to find the exact match at the address level.

**To find a prescriber, use one of the following three search options:**

1. Last name + DEA #
  - When filling controlled substances, stores should use the DEA number for search and validating address information in RxConnect matches what is documented on the hardcopy.
2. Last name + NPI #
3. Last name + telephone number



**In addition to the refined searches, RxConnect will provide Pharmacy colleagues with messages/alerts when:**

- A selected prescriber's record has been flagged for federal or state issues.
- A prescriber may be limited in their controlled drug prescribing ability.
- A prescriber may be deceased, sanctioned, have an expired DEA license, etc.



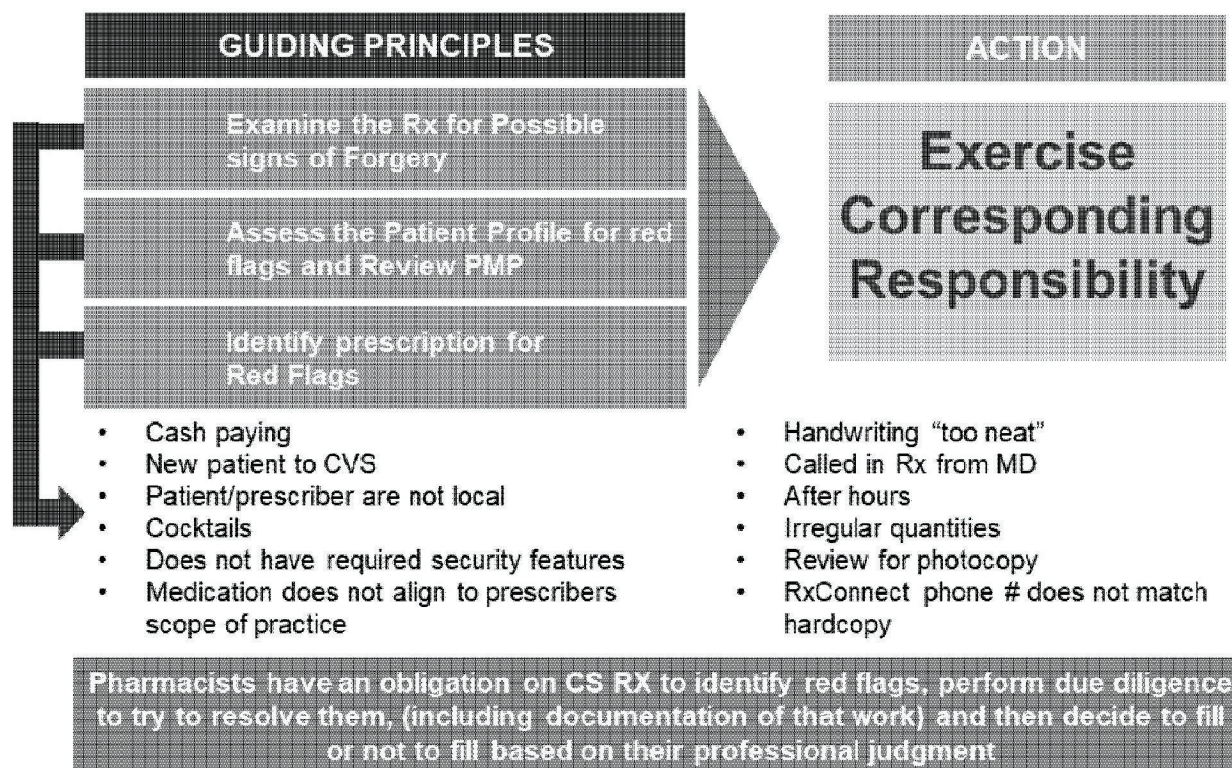
When communicating to patients about the content of these alerts, it is important to be precise about the issue that was flagged and not elaborate beyond the alert information.

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## Forged or Altered Prescriptions

Before filling a prescription, Pharmacy colleagues must be satisfied that, the prescription meets all valid requirements. Below are tips to identify a fraudulent prescription.

### Tips to Identify a Forged Controlled Substance Prescription



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## Forged or Altered Prescriptions, Continued

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### Contacting the Prescriber

If you need further prescription validation, contact the prescriber to verify a prescription:

- Use the phone number in RxConnect if that number differs from the phone number on the prescription.
- Note the name of your contact at the prescriber's office and summarize the conversation in the RxConnect patient notes.
- If the prescription cannot be verified, it cannot be filled.
- In some states, only tamper proof prescription forms may be used for CII drugs. It is important that Pharmacy colleagues dispense based on correct prescription forms.
- If a prescriber verifies that a prescription has been forged, altered or is otherwise invalid:
  - The prescription must not be filled and should be made inactive RxConnect if it has already been data entered or verified. **At no time should a prescription ever be deleted.**
  - If applicable, any claim should be reversed.
  - Inform the patient that the prescriber has instructed them to not dispense the medication and that you cannot return the prescription to them.
  - Note: if the patient becomes confrontational/hostile, a copy of the prescription should be made and the original can be provided back to the patient.
  - Follow state law around giving the prescription back to the patient. If the original cannot be retained, a copy of the prescription should be retained if possible.
  - Review and follow the steps documented in the CVS Pharmacy Prescription Forgery Protocol outlined on the next page.

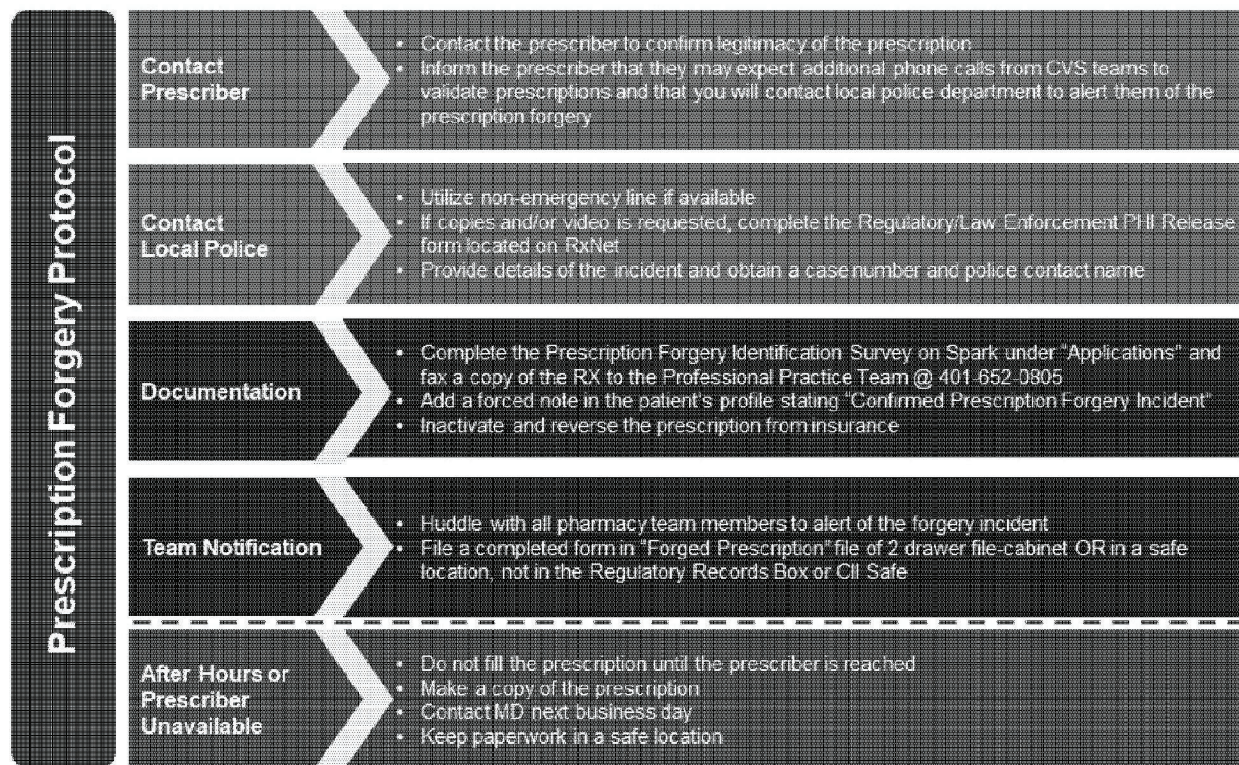
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**Forged or Altered Prescriptions, Continued**

Compliance → Legal and Regulatory → Controlled Substances/Recordkeeping  
 → Controlled Substance Resource Page → Fraud → Prescription Forgery Protocol  
 Job Aid

**Pharmacist on Duty Role/Responsibility**

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CVS Health

**Governing Principles**

After speaking with the prescriber, do not dispense a prescription that, in your professional judgment is forged, altered, or otherwise invalid.



Filled prescriptions that are later discovered to be forged or altered must be reported as outlined in the CVS Pharmacy Prescription Forgery Protocol, notify the District Leader/Pharmacy Supervisor and local law enforcement.



**FLORIDA STORES ONLY:** Any use or attempted use of a prescription that is known or believed to be forged or altered must be reported to the local sheriff **within 24 hours**. The report must include a copy of the prescription, narrative documenting contact with the prescriber, identifying information regarding the customer, and surveillance video or photographs.



## Prescription Requirements

### Schedule II Prescription Requirements

The following standards apply when accepting Schedule II (CII) prescriptions:

- Unless the prescription is for an emergency or a resident of a long term care facility or hospice, CII prescriptions may not be dispensed until the Pharmacy receives the original prescription (even if a faxed copy was received in advance).
- Must be in writing and manually signed by the prescriber; the original prescription can be an e-prescription in states where electronic prescribing is approved.
- A partial fill for a CII is allowed if a Pharmacist cannot supply the full quantity written, if the Pharmacist notes the quantity supplied on the prescription and the remaining portion is dispensed within seventy-two (72) hours. If the remaining portion cannot be filled within this time, to dispense an additional supply the Pharmacist must notify the prescriber and get a new prescription.
- Dispensing two prescriptions from one CII hard copy due to insurance restrictions is NOT allowed (i.e. Prescription is written for Oxycodone 5mg #180 and two prescriptions are processed, one for #120 and a second is processed for #60).
- If a patient or prescriber requests a smaller amount be dispensed than prescribed, the pharmacist may dispense the smaller amount, but the balance becomes void and a new prescription would be needed to dispense an additional supply.
- Partial fills may also be allowed for patients in long-term care facilities or with terminal diagnoses. This usually requires proper documentation on the prescription and may not be permitted by your state's law.

- Federal law permits an emergency CII prescription to be phoned into the Pharmacy, with the amount dispensed limited to that necessary to treat the patient during the emergency period.



**Note:** company policy further restricts the maximum supply that may be dispensed in this situation to a seventy-two (72) hour supply. *Some states may not allow the practice of telephoned emergency CII prescriptions or may impose a stricter quantity limitation.*



If the Pharmacy does not receive the written prescription within seven (7) days to cover the phoned in emergency prescription, the Pharmacy team must notify the DEA. *State laws may have a time limit shorter than 7 days and additional reporting requirements.*



RxConnect helps Pharmacists recognize when an emergency telephoned CII prescription requires follow-up with the Prescriber or DEA outreach. These "Phone CII" notifications will appear with the Prescriber Calls in the Verification Queue (QV) and can be accessed in the Request Queue (QR). Document all action outcomes for these Phone CII items. For more information, please refer to LEARNet course 204247 Telephone CII Follow Up Enhancements.

**Important:** Many state laws are imposing stricter day's supply limitations on CII prescriptions. Pharmacists **must** adhere to their state's law regarding quantity restrictions, and if your state has laws that are more stringent than the federal regulation, the state laws **must** be followed.

*Continued on next page*

**Prescription Requirements, Continued**

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**Schedule III-V Requirements**

Schedule III – V (CIII – V) controlled substances may be dispensed pursuant to the following:

- A written prescription signed by the prescriber.
- An electronic prescription, where e-prescribing is permitted by state law.
- A faxed prescription, provided the original fax is manually signed by the prescriber.
  - For faxed prescriptions, electronic or typed signatures are not valid.
- An oral prescription provided the prescription is promptly reduced to writing by the Pharmacist and contains all information on a written prescription except the signature of the prescriber.
  - Maintain verbal prescriptions with other CIII-V prescriptions.

**Note:** If your state law is more stringent than the federal regulation, follow state law.

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**Electronic Prescriptions (eRx)**

In order to send or receive an eRx for a controlled substance, the prescriber and Pharmacy must both have a certified ePrescribing system (if authorized under your state's law).



RxConnect (RxC) has the ability to receive electronic prescriptions for controlled substances from certified prescribers.

Upon receipt of an eRx for a controlled substance:

- RxConnect checks the prescriber's certification and contents of the eRx for all required information.
- If the required information is provided, the eRx will be placed in the workflow for processing.

There will be instances in which an eRx for a controlled substance will be rejected because the prescriber is not certified to transmit a controlled substance eRx or the prescription data elements do not meet all requirements for a controlled substance prescription.

Important: RxConnect cannot determine if a prescription was written for a legitimate medical purpose. That determination remains the responsibility of the dispensing Pharmacist.

In cases where the eRx is rejected:

- RxConnect will reject the eRx and place it into workflow as an "Invalid eRx".
  - The Pharmacy is required to follow up with the prescriber and obtain a written, fax or telephone prescription depending on whether it is a CII or a CIII-CV.
- 

**Transferring On-Hold Prescriptions**

Federal DEA regulation 21 CFR §1306.25 permits the electronic (only) transfer of CIII-CV prescriptions for REFILL purposes.

CVS retail locations prohibit the practice of transferring new e-Rx's, as RxConnect is not currently able to electronically forward or receive forwarded electronic prescriptions.

**There are no workarounds.**

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## Prescription Requirements, Continued

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### **Use of Prescriber Phone Apps to Fax Controlled Substance Medication**

Prescribers have begun to securely fax prescriptions for controlled substances using either the RingCentral or Doximity phone app.

**However, neither method meets the federal criteria required for a valid faxed or electronically transmitted controlled substance prescription because they are not properly signed.**

If your store receives a faxed prescription sent using either the RingCentral or Doximity application, the Pharmacist must:

- Call the prescriber to inform them that the faxed prescription does not meet the federal criteria required for a controlled substance prescription fax.
  - For CIII-CV medications, obtain an oral prescription for the medication and immediately reduce to writing.
  - If the prescription was for a CII medication, inform the prescriber that a written hard copy prescription is required prior to fulfillment.
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## Dispensing Requirements

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### Corresponding Responsibility

#### Guidelines for Dispensing Controlled Substances:

It is required that a controlled substance prescription was issued for a legitimate medical purpose by a prescriber in the course of their professional practice. A Pharmacist must only dispense controlled substances with valid prescriptions that comply with federal and state laws. Pharmacists have a “**corresponding responsibility**” under federal law to make sure that any controlled substance prescription filled was written for a legitimate medical purpose.

CVS Health expects and supports all decisions by its Pharmacists to not fill prescriptions as long as, they are adhering to their corresponding responsibilities (mentioned above).

The CVS Health Guidelines for Dispensing Controlled Substances provides guidance for Pharmacists filling controlled substance prescriptions. All Pharmacists should be familiar with the guidelines and be mindful that their corresponding responsibility applies to the dispensing of any controlled substance.

#### Important guidelines for Pharmacists:



- Pharmacists must resolve all concerns associated to any controlled substance prescription from a practitioner that they have reason to believe has not been issued for a legitimate medical purpose or in the course of a valid doctor/patient relationship, regardless of whether the prescription is otherwise “valid” on its face. A Pharmacist should notify their Field Leader or DPPL if they notice a concerning pattern of prescribing by one specific doctor.

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## Dispensing Requirements, Continued

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### Corresponding Responsibility Red Flags

The following is a non-exclusive list of examples of red flags that must be resolved before filling a prescription for a controlled substance:

-  Large number of controlled substance prescriptions written by a single prescriber or practice.
-  Prescriptions written for unusually large quantities of controlled substances.
-  Prescriptions written by a particular prescriber that contain uniform dosage and quantities.
-  The use of prescriptions that are preprinted or stamped.
-  Issuance of prescriptions for antagonistic purposes (depressant and stimulant) at the same time.
-  Prescriber repeatedly issues new prescriptions or refills for controlled substances to a patient once the injury has healed.
-  Prescriber routinely prescribes the same combination of drugs for pain treatment, particularly where the DEA has identified that combination as having a high potential for abuse (i.e., oxycodone, alprazolam, carisoprodol).
-  Practitioners who you are aware do not take insurance or whose patients have insurance, but always insist on paying cash for their prescriptions.
-  Customers who request drugs by brand name, description or "street name" (i.e., Mallinckrodt blues or "blues").
-  If the prescribing of narcotics does not fit with the prescriber's practice or specialty area.
-  Practitioners who do not have privileges at local hospitals or who are, or have been, the subject of criminal investigation.
-  Prescriptions written by local prescribers for out-of-state patients or patients not local to the Pharmacy.
-  Prescriptions for a controlled substance written for multiple members of one household.
-  Customers who come to the Pharmacy in groups to get narcotic prescriptions filled.
-  Disconnect between patient's age, other patient profile information, and the type and quantity of the drugs prescribed.
-  Customers who appear visibly altered, intoxicated or incoherent.

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**Dispensing Requirements, Continued****Corresponding  
Responsibility  
Red Flags,  
continued**

Pharmacists should ordinarily only fill prescriptions if both the patient and practitioner reside within the geographic area served by the Pharmacy. There may be exceptions (i.e., patient travels a significant distance to see a cancer specialist), but exceptions should be limited, reasonably explained, and documented in the patient files. Document communications with a prescriber or investigator regarding these exceptions on the back of the prescription and include date, time, outcome, and name of the person spoken to.

**Contact the practitioner to verify the prescription:**

- With any concerns about the type and quantity of medication prescribed for a given indication.
- If the prescription appears to be duplicative therapy, refilled too soon, or if the patient has had a prescription issued by several practitioners.
- Where you have no relationship with the patient and/or prescriber.

**Note:** Verification of a prescription with the prescriber is not sufficient to satisfy a Pharmacist's corresponding responsibility to dispense prescriptions written only for a legitimate medical purpose.

**Prescription  
Dispensing**

- The dispensing of controlled and non-controlled substances to Prescribers for the purpose of "office use" is strictly prohibited under Federal Law and Company Policy.
- Under no circumstance should a Pharmacist fill a controlled substance prescription written "for office use", "for doctors bag", or in any other manner that suggest that the medication is to be used as a supply for the Prescriber's practice.
- Prescriptions for controlled substances can only be filled for a bona fide patient (i.e. the intended end-user of the medication).
- All controlled substances must be dispensed to a member of the patient's household, either the intended end user or a family member/caregiver of the end user.
- Reminder: Company Policy prohibits the filling of controlled substance prescriptions that are written by a prescriber: 1) for themselves or 2) for a member of their family.
- Family Members are defined as a spouse, parent, child, sibling or other individual in relation to whom a Pharmacist/Prescriber's personal or emotional involvement may render that physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.
- Furthermore, CVS policy prohibits Pharmacists from verifying controlled substance prescriptions issued to themselves or family members.



## Refusal to Fill

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**Refusal to Fill** Pharmacists are one of the most trusted healthcare professionals. When they determine it is inappropriate to fill a narcotic prescription, they have an obligation to inform their patients of their decision as to why they are not able to fill it. Please follow your state law.

**In situations where a Pharmacist may refuse to fill a narcotic prescription, they must:**

- Deliver the information directly to the patient: Pharmacists should use the four attributes of PERC in the conversation.
- Professional, Engage the patient in the conversation, Respectful, Clear communication.



Review the **Refusal to Fill job aid** on the next page to help you when having refusal to fill conversations with patients.

**Important:** Under no circumstance should a Pharmacist refer a patient for whom they have refused to fill a narcotic prescription to another Pharmacy or another Pharmacist.




RxNet → Compliance → Legal and Regulatory → Controlled Substances / Recordkeeping → Controlled Substances Resource Page → Corresponding Responsibility.

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*Continued on next page*

**Refusal to Fill, Continued**

Refusal to Fill Conversation Guide		
<b>THE GOAL</b>  For a Pharmacist to consistently deliver the “refusal to fill” message to a patient in a responsible, professional manner so the patient understands the reason for the refusal and next steps.		<b>THE PLAN</b>  Use the 4 attributes of PERC (Professional, Engage the patient, Respectful, and Clear communication) in the conversation. Be prepared to give the patient specific reasons for the refusal, phrased in easy to understand language, and consider the patient’s point of view.
	<b>What you’re tempted to say</b>	<b>What to say instead</b>
<b>Start</b>	<ul style="list-style-type: none"> <li>• I am sorry. I cannot fill this prescription for you.</li> <li>• Your prescription is too early to fill. This is our company policy.</li> <li>• I see in your profile that you have seen multiple prescribers in the past few months for this controlled substance.</li> </ul>	<ul style="list-style-type: none"> <li>• Hi, my name is ____; I am the Pharmacist in this store. Do you have a few moments for us to discuss this prescription?</li> <li>• I understand you really want to fill this prescription. I would like to get a better understanding of your situation.</li> <li>• Are there any extenuating circumstances that I need to know about your condition?</li> </ul>
<b>Middle</b>	<ul style="list-style-type: none"> <li>• I am not comfortable filling this prescription.</li> <li>• We are out of stock of this medication. OR</li> <li>• There are too many red flags so I cannot fill your prescription. OR</li> <li>• The prescriber is too far away from this store.</li> <li>• It is my decision. It is your problem.</li> </ul>	<p>As a Pharmacist, I must use my professional judgment on an individual basis when filling prescriptions to support our patients’ health and well-being.</p> <p>This is uncomfortable for the both of us but I want to respect and be honest with you. We are not able to fill your prescription because (options):</p> <ul style="list-style-type: none"> <li>• Of the combination of medications prescribed.</li> <li>• It is too soon to fill, has there been a change?</li> <li>• It is prescribed above recommended dosage.</li> <li>• You have seen multiple prescribers for the same therapy.</li> </ul> <p>I want you to know this decision is not personal. I am sorry if this feels unfair.</p>
<b>End</b>	<ul style="list-style-type: none"> <li>• Go back to your local store. You are not one of my regular customers. We are saving the medication for our regular customers.</li> <li>• I do not have any more time to discuss this.</li> <li>• I do not have anything more to say. You can call 1-800-SHOPCVS.</li> </ul>	<ul style="list-style-type: none"> <li>• (If options are available to the patient such as calling the prescriber) I would like to be able to help you. Are you open to discuss options?</li> <li>• What additional questions do you have for me? Do you understand why we are not filling your prescription today?</li> <li>• I appreciate your time to discuss this with me. I apologize again and know this is difficult for you, but I cannot fill your prescription today.</li> </ul>

**Note:** If you or your colleagues are being harassed or feel a serious threat, notify the manager on duty and contact your District Leader/Pharmacy Supervisor immediately. If you find yourself in an emergency, call the local police.

## Prescription Drug Monitoring Program

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### Overview

#### Prescription Drug Monitoring Program

A Prescription Drug Monitoring Program (PDMP, also known as PMP) is an invaluable tool for a Pharmacist to help reinforce their obligation to prevent controlled substances from being diverted or dispensed for non-medical purposes, while at the same time ensuring patients with legitimate medical needs continue to have access to these products.

Pharmacists must review each prescription and:

- Identify red flags and perform due diligence to determine if the red flags can be resolved.
- Assess all the information provided to make a sound professional judgment in determining whether or not to fill the prescription.

All states, except PR and part of MO, have implemented PDMPs, also called Prescription Drug Monitoring Programs (PDMPs) that require pharmacies to report dispensed prescriptions for controlled substances and other drugs. While Pharmacy Operations reports on behalf of the stores, store teams have the responsibility to ensure that data entry is complete and accurate.



Only Pharmacist and Grad Interns can access the state PDMP website per CVS Health policy.

- The structure and requirements for each state vary. Some states provide access to Pharmacists and practitioners to review a patient's profile or a doctor's prescribing patterns.
- Some states require that a Pharmacist consult the PDMP before dispensing certain medications.
- The information contained within the PDMP website should be used by the Pharmacist, as appropriate, to assist in exercising professional judgment/corresponding responsibility when evaluating a controlled drug prescription.



**Important:** In states where Pharmacists are not required but may be granted access to review patient profiles or physician prescribing patterns, CVS Pharmacy requires all Pharmacists to register for access and develop a store protocol for regular monitoring.



Further information and guidelines can be found on **RxNet → State Specific PMP**

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## Verifying the Identity of the Recipient of Controlled Substances

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### **Ultimate Users**

Under federal law, only dispense a prescription to an "ultimate user."

This means that it may be given to the person for whom it was prescribed or a member of their household or for an animal owned by them or by a member of the household.

Therefore, Pharmacy colleagues must be satisfied that the medication will not be diverted.

To do so, you should verify the identification of the person picking up the prescription. You can verify that the person picking up the prescription is a member of the household by, for example, asking their address or other identifying information.

If the state your Pharmacy is located in does not have specific requirements, you may still ask for identification to assist in ensuring that a prescription will not be diverted. It is the responsibility of the Pharmacy team to be aware of any state requirements relating to verifying the identity of a person picking up a prescription.

The following states have specific requirements. Review the requirements that apply to your location.

AZ, CT, DC, DE, CA, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MI, ME, MN, MS, NC, ND, NH, NV, NM, NY, OH, OK, PA, SC, TX, UT, VT, VA, WA, WI, WV, & WY.

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## Controlled Substance Refills

### Requirements for Multiple CII Prescriptions



**Note: Schedule II prescriptions may not be refilled.**

In some cases, DEA regulations allow practitioners to write multiple prescriptions for Schedule II drugs (e.g., methylphenidate) to be dispensed over a number of months. To be valid, such multiple prescriptions must meet the following requirements, among others:

- The total amount prescribed and dispensed pursuant to all of the prescriptions must be limited to a 90-day supply with the original date written and the subsequent prescriptions should state "Do not fill until (date)".
- Date on the prescription should not be predated.
- Each prescription must be issued on a separate prescription blank.
- Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice.
- The practitioner must provide written instructions on each prescription indicating the earliest date the Pharmacy may fill the prescription.
- The first of these multiple prescriptions, if devoid of any "Do not fill until (date)" instruction, may be filled immediately.
- The issuance of multiple prescriptions must be permissible under applicable state law. Many states limit the prescribing of Schedule II drugs to a 30-day supply.

This is not permissible in all states. Remember, the more stringent requirements must always be followed.

### Requirements for CIII-V Refills

#### Handling CIII – V Refills:

Schedule III-IV prescriptions may be refilled if authorized on the prescription. However, under federal law, the prescription may only be refilled five times within six months after the original date of issue. After five refills or six months, whichever comes first, a new prescription is required. Remember that state law may be more restrictive. Under federal law, Schedule V prescriptions may only be refilled if authorized on the prescription by the prescriber.

**Note:** Some states impose additional limits on controlled substance refills. Partial refills are permitted in some states, but never beyond the 6-month time limitation from the date the prescription was written.

### Requirements for Early Refills

It is probable, for drug seekers or criminals to refill a prescription early as a means to obtain additional amounts of the controlled substances. Pharmacy colleagues should not refill controlled substance prescriptions early unless they can document a legitimate reason for doing so. CVS Health colleagues must be vigilant and exercise sound judgment in each individual case to determine that refilling a prescription early is appropriate and is not a means of facilitating diversion.



RxNet → Policy and Procedure → under Controlled Substances/Recordkeeping → Early Fill of Controlled Substance Prescriptions Policy (ROPP-048255)

*Continued on next page*

## Controlled Substance Refills, Continued

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### Ordering and Receiving Requirements



CVS Health's policy restricts refills for controlled substance to not more than two (2) days prior to the previous supply being exhausted based on last pick up date. Fills earlier than two (2) days require physician authorization and Rx Connect documentation.

**Note:** Certain states impose other, sometimes stricter, limits on early fills.



#### Process to Follow:

**Note:** the Managing CII's and CIII-CVs job aid below.



RxNet → Compliance → Legal & Regulatory → Controlled Substances/Recordkeeping.



**Note:** To meet all State & Federal Requirements in regards to controlled substances, it is important to know that all regulatory and record-keeping processes listed below will remain the same for stores on CFRx. The CFRx check-in process only acts as a BOH update.

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## Ordering Requirements for CII and CIII-CVs

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### Expectations for Ordering CII

Order schedule II controlled substances (CII) with an official DEA order form (DEA Form 222). **Only Pharmacists that have been granted a valid Power of Attorney (POA) can execute a DEA Form 222.** Keep all executed POA forms on file at the Pharmacy in which the POA is executed.

**It is imperative that once you receive these forms, you ensure that they contain your store's address and DEA information. It is also required that these forms are stored, submitted and filed properly.**

Use forms in sequential order. File executed and voided DEA Form 222s in the Regulatory Records box in sequential order with the invoice attached. Secure blank DEA Form 222s in the CII safe.

**Note:** there will be no invoice if the DEA Form 222 is voided.

**The Pharmacist granted POA at the time an order form is being submitted to the Outside Vendor (OV) is the only one who can sign the DEA Form 222. Do not pre-sign or store the DEA Form 222 allowing other Pharmacists who do not have POA to place CII Orders.**

When submitting a CII order, the DEA Form 222 must be signed and dated by a Pharmacist who has been granted a POA for that specific location/registration by CVS Health.

Copies of the DEA Form 222 must be distributed as follows:

- Copy 1 and Copy 2 are submitted to the supplier.
- Copy 3 is retained in the Pharmacy's files in the Regulatory Records box for a period of 2 years (unless longer retention is required under state law).
- Executed DEA Form 222s must be maintained separately from the Pharmacy's other business records in sequential order.

**Note:** Many states require transactions that involve substances that are classified as a Schedule II drug on a state schedule, but not on the federal schedule, be recorded on a DEA 222 form.

*Additional information regarding DEA Form 222s can be found on RxNet.*



RxNet → Compliance → Legal & Regulatory → DEA 222 Process.

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## Receiving Requirements for CII and CIII-CVs

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### Steps for Receiving CII Orders

At CVS/Pharmacy, **only a Pharmacist** must receive and check in CII orders, using the steps detailed below.

#### STEP 1



**Before** signing for receipt of the CII order, **check the tote/tray** containing CII drugs while the driver is still at the store. If it appears that it may have been tampered with (e.g., tote/tray appears to be damaged or is not sealed) OR if when you reconcile the order invoice to the amount in the tote/tray, there is a discrepancy, the Pharmacist checking in the controlled substance must:

- Refuse the order and do not sign the delivery log.
- Notify the driver that the shipment is being refused.
- Report the discrepancy to your Field Leader, Asset Protection and the appropriate outside vendor.

#### STEP 2



If there is no discrepancy or evidence of tampering, the Pharmacist signs-off on the driver's delivery log and completes the following CII receiving procedures.

#### STEP 3



Immediately upon checking-in the order, the Pharmacist signs and dates the DEA Form 222 and completes the following information for **each line** of the Pharmacy's copy of the DEA Form 222:

**Note:**

*If a product was not shipped, a "0" should be placed in the quantity-received section and date received should reflect the date the rest of the order was received.*

As a distributor, Cardinal has an obligation under the Controlled Substances Act to review all orders for controlled substances received from Pharmacies prior to fulfillment and delivery. Occasionally, a partial order or single item may be held by Cardinal pending further research and review. When this occurs, product shipment is delayed and the invoice is updated with the following text as a means of store notification: "Held Pending Regulatory Review." The hold on the order will last no more than 24 hours and that item may be either cancelled or released. If the items are released, the product will ship to the Pharmacy on the next business day along with the appropriate invoice. **This process does not occur with McKesson.**

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*Continued on next page*

**Receiving Requirements for CII and CIII-CVs**, Continued**Steps for Receiving CII Orders, Continued****STEP 3**  
(continued)

**Pharmacists** must pay close attention to the Cardinal invoice in the case where a CII order is delivered and not all products expected are received.

**For items not received:**

- If the invoice is marked with “Held Pending Regulatory Review,” the receiving Pharmacist should enter a zero “0” in the packages shipped field of the DEA Form 222 until the outcome of the Regulatory Review is determined on the next business day.
- In the case that the product is subsequently released and delivered, the DEA Form 222 should be completed with the actual amount and date receipt.

- Should the item(s) be cancelled, the store should then complete the DEA Form 222 with a zero “0” in the packages shipped field and document the date of the original order delivery.

**Important:** Items are not held and shipped later in any other case, such as temporary out of stock situations.

**Note:** “Ditto marks” [“] are not valid, complete the quantity and the date received for each medication that is listed on the DEA Form 222.

The use of “ditto marks” and failure to correctly fill out the DEA Form 222 can result in fines to the Pharmacy.

**BLANK DEA FORM 222**  
**U.S. OFFICIAL ORDER FORM - SCHEDULES I & II**

See Reverse of FORM 222 for  
Copy of Instructions

Order form may be used for Schedule I and II substances upon a  
registered application (see Section 301.135 of the Code of Federal Regulations)

DEA APPROVAL  
No. 1817-0010

TO: (Name of Supplier) STREET ADDRESS

CITY AND STATE DATE

TO BE FILLED IN BY PURCHASER

1	2	3	4	5	6	7	8	9	10
No. of Packages	Date of Package	Name of Item	Initials and Date	Package	Shipped	Date	Shipped		
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

LAST LINE COMPLETED (NOT FOR PURCHASER) SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT

Date Received DEA Registration No. Name and Address of Registrant

Schedule

Quantity and Date

DEA Form 222 (Rev. 10/02)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II  
DEA'S ENFORCEMENT ADMINISTRATION  
SUPPLY OF 10 Copies

(Some states require additional notations on the DEA Form 222. The Pharmacist must be familiar with the regulations in your state.)

(Some states, for example, DC, require the NDC portion to be filled in.)

*Continued on next page*



## Receiving Requirements for CII and CIII-CVs, Continued

## Steps for Receiving CII Orders, Continued

## STEP 4



Staple the packaging slip or order invoice to the back of the DEA Form 222 and file in the appropriate folder in the Regulatory Records box in sequential order by serial number.

Below you will find a correctly filled out example of a completed DEA Form 222.

See Reverse of PURCHASER'S Copy for Instructions			No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04)										OMB APPROVAL No. 1517-0010		
TO: Name of Supplier <i>Cardinal Health</i>			STREET ADDRESS <i>14 Supplier Rd</i>												
CITY and STATE <i>Anytown, RI</i>			DATE <i>7/7/2014</i>			NATIONAL DRUG CODE					TO BE FILLED IN BY PURCHASER				
LINE NO.	No. of Packages	Size of Package	Name of Item	NATIONAL DRUG CODE										No. of Packages Received	Date Received
				1	2	3	4	5	6	7	8	9	10		
1	8	100	<i>Oxycodone APAP 5-325 mg</i>											8	7/9/14
2	2	100	<i>Oxycodone 30mg</i>											2	7/9/14
3	2	5	<i>Fentanyl 25 mcg/hr patch</i>											2	7/9/14
4	1	100	<i>Methylphenidate 10 mg</i>											1	7/9/14
5	4	100	<i>Oxycodone 5mg</i>											4	7/9/14
6	2	100	<i>Methylphenidate ER 36 mg</i>											2	7/9/14
7	1	100	<i>Oxycontin 20 mg</i>											1	7/9/14
8															
9															
10															
7 LAST LINE COMPLETED (MUST BE 10 OR LESS)			SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT <i>Jane Smith</i>												
Date issued <i>06/01/2014</i>			DEA Registration No. <i>SC000000000</i>			Name and Address of Registrant <i>CVS PHARMACY, LLC OF ANYSTATE DEA: CVS/PHARMACY #000000 1 CVS DRIVE WOONSOCKET, RI 02895</i>									
Schedules <i>2, 2b, 3, 3b, 4, 5</i>															
Registered as a <i>CHAIN PHARMACY</i>			No. of this order form <i>123456789</i>												
DEA Form - 222 (AUGUST 2013)			U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II DRUG ENFORCEMENT ADMINISTRATION PURCHASER'S Copy 3												

## STEP 5

The Pharmacist must also check-in the delivery through the Electronics CII Perpetual Inventory.



**Note:** Per CVS policy, Pharmacists are responsible for conducting an inventory each calendar month of all CII drugs, unless otherwise specified by state regulation (e.g., every 10 days in MA).

Continued on next page

**Receiving Requirements for CII and CIII-CVs, Continued**

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**Receiving CIII – CV Orders**

**Note:** To meet all State & Federal Requirements in regards to controlled substances, it is important to know that all regulatory and record-keeping processes listed below will remain the same for stores on CFRx. The CFRx check-in process only acts as a BOH update.

**CIII - CVs  
Receiving  
Requirements**

When receiving CIII – CVs as part of a Warehouse delivery or from an Outside Vendor, the following is required:

**For Warehouse Deliveries:**

- Pharmacy staff\* must verify that the number of totes/trays that were delivered matches the number listed in the delivery paperwork.
- Pharmacy staff\* must ensure the totes are sealed and not tampered with. If tampering is suspected, the order should not be accepted. **This also applies to Outside Vendor (OV) Deliveries.**



RxNet → Policy and Procedure → under Inventory Maintenance → Pharmacy Warehouse Delivery policy (ROPP-045478).

- The Pharmacist or Pharmacy Technician checks in controlled drugs received from the warehouse or OV piece-by-piece, against the appropriate invoice using a verification symbol (e.g., checkmark, circle, slash, etc.).
- Acknowledge each individual NDC on the invoice as received via a checkmark or other written confirmation of receipt next to the quantity shipped on the invoice.
- The invoice is then reviewed and the Pharmacist (or in certain states where it is allowed, a designated Pharmacy Technician) must sign and date the invoice as written confirmation of designation when complete. The Pharmacist should recognize the correct quantity was received and the inventory level is appropriate to dispensing.
- **Report all overages, shortages and mispicks from weekly warehouse deliveries to Distribution Services at 401-770-5555 within 24 business hours of the delivery.**

**Note:** \*Pharmacy Technicians are not allowed to perform this task in all states.

*Continued on next page*



**Receiving Requirements for CII and CIII-CVs, Continued****Completing  
a CIII - CV  
Invoice****Sample Outside Vendor Invoice (CIII-V).**

QUANTITY	ITEM DESCRIPTION	EXTENDED AMOUNT
1	4180750001	\$ 68.30
1	4180750002	\$ 339.00
1	4180750003	\$ 618.80
1	4180750004	\$ 590.24
1	4180750005	\$ 818.50
1	4180750006	\$ 11.20
1	4180750007	\$ 11.20
1	4180750008	\$ 11.20
1	4180750009	\$ 11.20
1	4180750010	\$ 11.20
	<b>INVOICE TOTAL</b>	<b>\$ 2,044.33</b>

**Requirements on each Outside Vendor Invoice (CIII-V):** (see image above)

- 1) Contains the signature of the person receiving (may be Pharmacist or Technician).
- 2) Contains the hand-written or stamped date received.
- 3) Each line contains a written quantity validation.

A checkmark, circling of the quantity or similar notation are all acceptable

Lines containing a zero "0" quantity received must still be acknowledged with a validation mark

Requirements for filling out this type of invoice:

- Must be stored chronologically within the appropriate monthly folder in the Regulatory Records Box.
- Invoice should be an original or if not available, a "replacement invoice".
  - Do not update replacement invoices printed due to the loss of the original invoice to contain receipt validation marks, date received or colleague signature.
- May be interspersed with Warehouse CIII-V Manifests.

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## Returning Requirements for CII and CIII-CVs, Continued

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### Steps for Returning CII to the Reverse Distributor

Review the steps below when returning CII to the Reverse Distributor:

**Note:** All CII returns are processed through INMAR/FedEx Supply Chain.

1. Verify that you have received a DEA Form 222 from INMAR/FedEx Supply Chain prior to returning a Schedule II.
  - Utilize INMAR/FedEx Supply Chain system for CII returns. Through this process, the request for the DEA Form 222 will be generated.
2. For returns, treat the Pharmacy as the supplier of the controlled substances and the DEA Form 222 supplied by INMAR/FedEx Supply Chain must be filled out and submitted accordingly.
  - For example, record the packages shipped, and date shipped on the form. Also record the store DEA number in the Supplier's DEA # field unless pre-printed.
3. As the supplier, the store must forward – **during the same calendar month** - Copy 2 (green copy) to the local DEA office and keep Copy 1 (brown copy) in the CII Return Invoices/Destruction Records folder of the Regulatory Records box.
4. Secure all CII returns in a quarantine section of the CII safe until the DEA Form 222 arrives from INMAR/FedEx Supply Chain and the return box is complete and ready for return.
5. Complete the CII return as per normal non-saleable returns process (INMAR/FedEx Supply Chain).

**Note:** Quantities on the documentation should be accurate, because discrepancies will trigger follow-up from INMAR/FedEx Supply Chain and potential loss reporting.



RxNet → Inventory and Merchandising → Non-Saleable Returns → INMAR.

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## Receiving Requirements for CII and CIII-CVs, Continued

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### **Returning CIII - CVs to the Reverse Distributor**

When returning CIII - CVs to the Reverse Distributor, utilize the Symbol (Telson Unit).

#### **INMAR/FedEx Supply Chain**

**Important:** Maintain a copy of the key rec in the CIII-V Return Invoices/Destruction Records of the Regulatory Records Box along with a copy of the UPS shipping label to validate the shipment date.

#### **StrongPak**

##### **Important:**

Keep one copy of each key rec and Product Transfer Schedule (PTS) for your records:

- The notated and signed StrongPak controlled key rec and PTS must be placed in the Regulatory Records box at time of pickup.

All shipments including pick-ups involving controlled substances by Stericycle must include the required DEA information which is contained on the Product Transfer Schedule (PTS).

Should any PTS documentation not be provided during pick-up or if any PTS documentation is lost, PTS reports can be viewed and printed on the Environmental Health and Safety Reports link via SPARK.

- The PTS must be reviewed and signed by the Pharmacist, at the time of pick up and attached to the StrongPak Controlled Substance Key Rec and retained in the CIII-V Return/Destruction folder in the Regulatory Records box.



RxNet → Non-Saleable Returns tab

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## Controlled Substance Record Retention Requirements (RRR)

### Annual Inventory

DEA requires a biennial inventory of all controlled substances on-hand at the pharmacy, which includes quarantined for return, destruction, or reverse distribution.

All CVS pharmacies perform this inventory annually after closing on April 30 or before opening on May 1. 24-hour locations must perform this inventory between midnight and 6:00am on May 1. *State laws may have different requirements and pharmacists must adhere to those.*

Completed annual inventories must include the appropriate completed cover sheet, with the name and signature of the pharmacist performing the count.

More information, forms, and instructions are located on RxNet.



RxNet → Inventory and Merch → CFRx Inventory → Controlled Substance Inventory (Biennial / Annual / PIC Change)

### Pharmacy Records Retention Requirements (RRR)

#### Pharmacy Records Retention Requirements:

- Federal and state laws impose strict recordkeeping requirements on pharmacies for the creation and maintenance of records relating to ordering, receipt, dispensing, and disposal of controlled substances.
- Federal law requires that a Pharmacy keep controlled substance records on site in the Pharmacy for 2 years. Federal law also requires that controlled substance records be readily retrievable and separate from non-controlled records. Separate Schedule II records from Schedule III-V records. **Significant fines can be imposed on a Pharmacy if every controlled substance record is not retained, acknowledged and properly maintained according to DEA requirements.**
- Various states require that Pharmacy records be kept for a period longer than the 2 years and may require that certain records be kept on site in the Pharmacy.
- It is the responsibility of all Pharmacy colleagues, and particularly the Pharmacy Manager, to be aware of the applicable state recordkeeping requirements and CVS Health Policy.
- Every Pharmacy must maintain complete and accurate records that comply with all applicable laws and regulations governing the content, manner and period of retention for controlled substance records.
- The Pharmacy Manager is responsible to ensure all requirements for Controlled Substance Recordkeeping are adhered to, including but not limited to:
  - Proper maintenance of an organized Regulatory Records Box, assembled and utilized per the instructions provided.
  - Proper execution and filing of DEA 222 forms.
  - Proper OV invoice/ WH manifest check in and filing procedures for controlled substance deliveries.



CVS Health policy requires the retention of various categories of records as set forth in the Document Retention Schedule.



RxNet → Policy and Procedures → Document Retention and Confidential Pharmacy Records Retention and Storage ROPP – 0029.

*Continued on next page*

## Controlled Substance (RRR), Continued

### Maintenance of Records and the Regulatory Records Box

#### Maintenance of Records:

All Pharmacy teams must utilize the Regulatory Records Box to ensure the proper storage and retention of all applicable information pertaining to controlled substances and regulatory matters.

The Regulatory Records Box provides a single storage location for the following:

- Copies of Store Licenses
- Copies of Employee Licenses
- POA's
- CII Annual Inventories
- CIII-V Annual Inventories
- Schedule II Change of Schedule Inventory
- Schedule III-V Change of Schedule Inventory
- CII Return Invoices / Destruction Records
- CIII-V Return Invoices / Destruction Records
- Drug Loss Reporting Forms
- California Quarterly CII Inventory Reconciliation
- Subpoenas
- Executed DEA 222 Forms; CII Invoices
- January-December: CIII-V Invoices/Manifests
- Regulatory Inspections
- Other State Required Records
- Off Site Record Storage Documents
- PSE Return Records
- PSE Manifests
- CII Change of PIC Inventory
- CIII-V Change of PIC Inventory

**Note:** Maintain records in the appropriately labeled folders contained in the box to maintain compliance. **The Pharmacy must not create additional folders or maintain other records in the records box unless approval is received from corporate.**

The Pharmacy must maintain this current year's box as well as last year's box in an easily accessible area within the Pharmacy area, so all records are immediately retrievable when requested during a DEA or Board of Pharmacy inspection.

**Note:** *Utilization of the Regulatory Records Box will also assist in the success of the Professional Practice Standards Review Regulatory Focus.*

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## **Controlled Substance (RRR), Continued**

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**Pharmacy  
Records  
Storage  
Requirements****Pharmacy Records Storage Requirements:**

All stores must have a space allocated, as determined by state law, for the storage and retention of confidential Pharmacy records. The Pharmacist on Duty and the Front Store Manager are responsible to ensure that a designated space is available and easily accessible.

The guidelines below must be met for storage areas:

- Kept organized and easily accessible at all times.
- The area must be clear of Front Store merchandise and Pharmacy supplies.
- Never leave prescription files or any other confidential records outside of boxes.

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*Continued on next page*



**Controlled Substance (RRR), Continued****Pharmacy  
Records  
Storage**

At present, no controlled substance records may be destroyed, but may be stored offsite where permitted by federal and state law.

**Requirements,  
continued**

**Important:** At no time should any confidential records and/or bags be stored outside the confidential waste bins.

**Prescription  
Hard  
Copy Filing:**

The next few pages explain the steps for filing hard copies as seen in the **Carolina Files job aid**

RxNet → Operational → Operational Support → Pharmacy Technology → Digital eRx Hardcopy Management FAQ → Page 5 (the first “click here”)

**Guidelines for Bundling / Filing Hard Copies in Carolina Files**

- Ensure back tags are applied in the same spot and direction on the back of every prescription to ensure easy filing and retrieval.
- File in numerical order, and secure each bundle of 100 prescription hard copies as you file using paperclips, rubber bands, etc.
- Ensure that your Carolina files are organized in sets of hundreds (e.g. xxxx00-xxxx99).
- CII, CIII-CVs, and non-controlled prescriptions should continue to be filed separately.

Here is a representative example of prescription number ranges you may encounter per Carolina file:

	Do eRx Hard Copies Print in Your State?	
	YES	NO
Non Controlled	300	1000-1500*
C3-C5	500	2000-3000*
C2	1000	4000-8000*

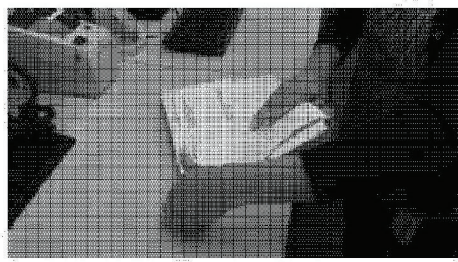
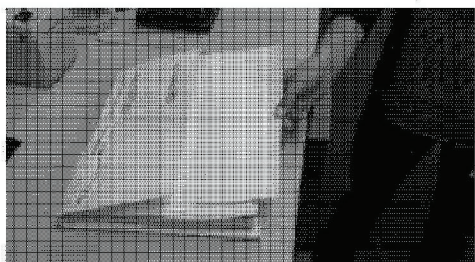
**\*Note:** Prescription number ranges may vary from under 1,000 to over 10,000 depending on your state eRx rate, store volume, and state laws for controlled substance prescriptions; regardless of the prescription number range per Carolina file, completely fill each Carolina file (approximately 300 prescription hard copies per Carolina file)

*Continued on next page*

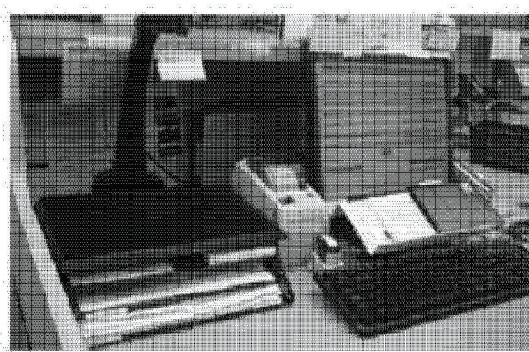
## Controlled Substance (RRR), Continued

### Carolina Files help you organize and bundle prescription hard copies

Carolina Files allow you to organize and bundle prescription hard copies without having to fold the prescription hard copies beforehand.



Tip: Placing filing trays under the scanner at Drop Off will help reduce clutter and promote a neat and clean Pharmacy environment.



*Continued on next page*



**Controlled Substance (RRR), Continued****Best Practices and Additional Information**

Filing and Boxing	<ul style="list-style-type: none"> <li>At Drop Off, prescriptions should be maintained in numerical order with back tags applied in the same orientation for ease of filing and retrieval.             <ul style="list-style-type: none"> <li>Place one labeled filing tray under the scanner for each drug class (non-control, CIII-CV) and file all prescriptions in the correct bin.</li> <li>Repurpose filing trays found in the Pharmacy to file and organize prescriptions. Stores without filing trays can order from the General Supply Guide (item number #553578).</li> </ul> </li> <li>Place one labeled filing tray under the scanner at Verification to file CII Hard Copies.</li> <li><b>Whenever possible, Carolina Files should be filed flat in the existing five-drawer filing cabinets.</b> <ul style="list-style-type: none"> <li>Stack completed Carolina Files five or six high. Two to three stacks will fit into each drawer.</li> </ul> </li> <li><b>Stores with non-working filing cabinets or extremely limited space may opt to file directly into boxes located under the counter or on the bottom uniweb shelf within the inventory bays.</b> <ul style="list-style-type: none"> <li>The updated box design has an attached lid which should not be removed.</li> </ul> </li> </ul>
Item Numbers	<ul style="list-style-type: none"> <li>Carolina Files - #438432</li> <li>Storage Boxes - #437863</li> <li>Filing Trays - #553578</li> </ul>
General	<ul style="list-style-type: none"> <li>If you have questions about Carolina Files, reach out to your District Leader/Pharmacy Supervisor for support.</li> </ul>



## **Diversions and Diversion Trends**

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**Introduction** Drug diversion occurs when legitimate prescriptions or legend drug products are diverted from their lawful purpose for illicit use. Drug diversion is a serious problem and is a focus of federal, state and local law enforcement.

**Drug diversion is a crime.**

Drug diversion also applies to products that contain pseudoephedrine/ephedrine (PSE/E). Drug diversion is against our value of integrity and will not be tolerated at CVS Health.

All Pharmacy colleagues are required to be vigilant to guard against the diversion of controlled substances and listed chemicals, including PSE/E products.

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**Examples of Diversion** If you steal drugs, you will be terminated from employment and may also be arrested and prosecuted. If you have a professional license, you may lose it.

All Pharmacy Managers have a responsibility to create an atmosphere and culture where all team members understand the policies and procedures to detect or deter diversion. Additionally, all Pharmacists assigned to pharmacies must understand their obligation to manage performance of and compliance to these policies. In partnership, Field Managers, Store Management, Pharmacy Team Leaders and all Pharmacists have an obligation to follow company procedures in order meet their obligations regarding diversion.

All drugs at CVS Health must be accounted for through valid prescriptions and proofs of purchase. All Pharmacy colleagues are required to be vigilant to guard against the diversion of controlled substances, listed chemicals and all prescription drugs.

Examples of diversion include:

**Internal theft**

- A colleague steals drugs from the Pharmacy.
- A colleague gives medication to a friend/family member without a valid prescription and/or without payment.
- A colleague manipulates Pharmacy systems to create a prescription for an unlawful purpose.
- A colleague self-medicates or ingests drugs from the Pharmacy without a prescription.

**Other examples of diversion include:**

- Robbery or night time break in.
- Prescriptions that are forged or altered.
- Prescriptions that were not written for a legitimate medical purpose by an individual practitioner, acting in the usual course of professional practice.
- Dispensing a prescription that does not comply with federal or state controlled substance laws.

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**Diversion and Diversion Trends, Continued**

- Consequences** Any colleague will be subject to disciplinary action up to, and including, termination if they:
- Divert prescription drugs or PSE/E.
  - Fail to comply with CVS Health policy on PSE/E products by:
    - Merchandising PSE/E product in a location other than behind the Pharmacy counter.
    - Processing a PSE/E transaction from a Front Store register, regardless of the reason (Pharmacy closed, or checkout lines are long).

**Drugs of Concern****Drugs of Concern:**

The Federal Drug Enforcement Administration (FDEA) has identified certain drugs as "drugs of concern." These drugs present a high risk for abuse or diversion and you should be particularly conscious of potential diversion issues when dispensing these drugs. You should also be alert to losses involving these drugs.

**Over-the-counter drugs containing dextromethorphan, such as Robitussin, Coricidin and PSE/E are also drugs of concern.**

Drug Type	Example Medications
<b>Opioids</b>	Hydrocodone, Oxycodone, Fentanyl, Hydromorphone
<b>Other Anesthetics</b>	Ketamine, Propofol
<b>Benzodiazepines</b>	Alprazolam, Clonazepam, Diazepam, Lorazepam
<b>Muscle Relaxants</b>	Carisoprodol, Cyclobenzaprine
<b>Stimulants</b>	Adderall and amphetamine salts
<b>Anabolic Steroids</b>	Testosterone, Stanozolol
<b>Other Drugs</b>	Codeine, Promethazine, Tramadol

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## Diversion and Diversion Trends, Continued

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### Diversion Trends

#### Diversion Trends:

Drug seekers and criminals may attempt to obtain controlled substances through many different means. Some examples are using forged or altered prescriptions, doctor shopping, pill mills, and even theft. We will discuss these trends in more detail in the next few sections.

**Remember that you cannot process a prescription that you believe to be forged or altered.**

**Important:** CVS Health colleagues must be vigilant and exercise sound professional judgment. If you have a question about any aspect of a prescription order, ask your Pharmacist.

**Consequence:** Knowingly dispensing controlled substances pursuant to an invalid prescription, including a prescription that is forged or altered is illegal. A Pharmacy colleague who fails to take steps to verify a prescription when there is reason to believe it is not valid and instead fills the questionable prescription can be prosecuted criminally and/or lose their professional license.

**Note:** Under no circumstances should a colleague attempt to detain a customer that presented a forged or altered prescription.

#### Requests to Participate in a “Sting” Operation:

Pharmacists should not fill a forged or altered prescription, even at the discretion of law enforcement.

If a Pharmacist is asked to participate in a “sting” operation, the Pharmacist must notify:

- Field Leader
- ProfessionalPracticeRetail@CVSCaremark.com

#### Doctor Shopping:

“Doctor shopping” refers to the practice of an individual visiting multiple doctors in order to obtain multiple prescriptions for a controlled substance. The individual will typically have the multiple prescriptions filled at different pharmacies. By doctor shopping, an individual can obtain a large quantity of controlled substances for purposes of abuse or diversion.

Best Practices to mitigate against diversion threat presented by doctor shopping are:



- When checking Patient Profile information, be alert for similar prescriptions filled at other CVS Health locations.
- If a Prescription Drug Monitoring Program is in operation in your state, please consult the available information. CVS Health strongly encourages its Pharmacists to use PDMP websites to assist them where appropriate in making an informed decision about whether or not to fill a prescription.
- If you identify duplicate prescriptions, notify the prescriber.
- If you have any question about whether a prescription was obtained for a legitimate medical purpose, attempt to verify with the prescriber. If you cannot verify the prescription, do not dispense the medication.

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## Controlled Substance Refills, Continued

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### Early Refills



- Strictly comply with applicable CVS Pharmacy policies and procedures regarding refills.

CVS Pharmacy policy restricts refills to no more than two (2) days prior to the previous supply being exhausted as measured by the last pick up date.

- Document attempts by a patient to obtain an early refill in the patient profile and consult the patient profile and Physician per CVS Pharmacy policy.
- Consider consulting the PDMP information available in your area, if applicable, to determine if this particular patient has demonstrated any pattern of making early refill requests at other pharmacies. If you determine it is appropriate to honor the early refill request, document the rationale and physician authorization for that determination as required in RxConnect.

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## Controlled Substance Refills, Continued

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### Pill Mills

#### Pill Mills and Rogue Pain Clinics:













Some doctors will prescribe large quantities of controlled substances to patients, with minimal medical evaluation.

- Watch for the red flags that are outlined below and exercise professional judgment.
- Merely calling the prescriber to confirm the prescription will not satisfy the Pharmacy's or staff's responsibility to ensure the prescription is for a legitimate medical purpose.

In areas where "Pill Mills" are prevalent, the ordering patterns for particular drugs with high abuse potential (i.e., hydrocodone or alprazolam) may increase, sometimes significantly.

**Important:** If a Pharmacy colleague is concerned about a potential pill mill, the colleague should report the matter to the **Ethics Line by calling 1-877-CVS-2040 (1-877-287-2040)**. Second, if you are comfortable doing so, inform your immediate supervisor of your concerns.

#### Some Red Flags of a Pill Mill operation include, but are not limited to the following:

-  Large number of controlled substance prescriptions written by a single prescriber or practice.
-  Prescriptions written for unusually large quantities of controlled substances.
-  Prescriptions written by a particular prescriber that contain uniform dosage and quantities for all patients.
-  The use of prescriptions that are preprinted or stamped.
-  Issuance of prescriptions for opposing medications (depressant and stimulant) at the same time.
-  Patient has traveled more than 20 miles to the Pharmacy.
-  Controlled substance prescriptions for multiple members of one household.
-  Customers who appear to be "high" or intoxicated.
-  Prescriber routinely prescribes a "cocktail" of prescriptions to a patient, e.g., oxycodone, alprazolam, carisoprodol, codeine and promethazine.
-  Patients who pay with cash.
-  Customers who come in groups to get prescriptions filled.
-  Customers who request drugs by manufacturer or street name (e.g., "Mallinckrodt blues" or "M's").

Pharmacists should be mindful that they have a "corresponding responsibility" under the federal regulations for the proper dispensing of controlled substances. A Pharmacist must ensure that any controlled substance prescription is valid before dispensing the medication.

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## Reporting Theft and Loss of Controlled Substances

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### Theft

Controlled substances and PSE/E listed chemicals may be the target of attempted thefts. This includes theft by a colleague (internal) or outside individuals (robbery or burglary).

Strictly comply with all applicable laws, regulations, and CVS Health policies and procedures regarding the security of the Pharmacy premises. Access to the Pharmacy is restricted and Pharmacy colleagues have the responsibility to ensure:

- Pharmacy doors are locked.
- Pharmacy access is restricted to authorized colleagues only and all approved vendors/non CVS Health colleagues are supervised while in the Pharmacy.
- Baseline Practices regarding Pharmacy security are followed including:
  - Personal belongings including bags, purses, jackets/sweaters or purchased items are kept in lockers, not in the pharmacy. Larger items should be stored in manager's office"
  - Remove or inspect Smocks when they are taken/worn out of the Pharmacy, unless the colleague is providing direct customer service.
- Strictly comply with all applicable laws, regulations and CVS Health policies and procedures regarding controlled substances, including the following:
  - Keep CII substances in the Pharmacy safe or narcotics cabinet.
  - Keys and safe combinations must be in the possession of authorized colleagues only. Assign alarm codes individually and do not share.
  - Secure and lock ALL Pharmacy safes or narcotics cabinets at all times.
  - Only authorized colleagues should have access to controlled substances.
  - Proper inventory receiving procedures are followed:
    - Pharmacists, not the Pharmacy Support Staff, are required to perform receiving procedures for CII substances. Pharmacy Support Staff\* may check in C3-C5 deliveries, but the invoice must be reviewed for accuracy and reasonableness, dated and signed by the Pharmacist on Duty or in certain states where it is allowed, a designated Pharmacy Technician.

\*Pharmacy Technicians are not allowed to perform this task in all states.

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## Reporting Theft and Loss of Controlled Substances, Continued

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Theft,  
continued



- Immediately report issues relating to theft through the appropriate channels.
  - In the event of a robbery or break-in, colleagues must follow CVS Pharmacy's policies and procedures regarding such events and must immediately report the incident to the local law enforcement authorities.
  - Report any suspected breach of Pharmacy security immediately to the Pharmacist on duty, the District Leader/Pharmacy Supervisor, a member of field management, Asset Protection and/or the Ethics Line.
- Immediately report all thefts/losses of controlled substances and PSE/E listed chemicals to the Pharmacist on duty to ensure timely submission of an Initial Notification and RAPM. **So the DEA and other relevant authorities can be notified in accordance with CVS Pharmacy's Reporting Theft or Loss of Controlled Substances/PSE/E Listed Chemicals Policy (ROPP-0064).** Including utilizing the Archer Drug Loss Program Database.



RxNet → Policy and Procedure → under Controlled Substances / Recordkeeping.

**Important:** Any suspected incidents of colleague diversion must be reported to an appropriate supervisor, RAPM/DAPL, District Leader/Pharmacy Supervisor, a member of field management or directly to the Drug Loss Program team at:  
***Drug\_Loss\_Program@cvscaremark.com.***

If you are uncomfortable reporting to the people above, call the **Ethics Line at 1-877-CVS-2040 (1-877-287-2040)** to anonymously report the incident or suspicion.

You are expected to report on suspicions or indications that diversion may be occurring. The Loss Prevention Department's role is to validate concerns and report findings to the appropriate parties. Handle all information discreetly and confidentially. There are times that you as a Pharmacist may be asked for information or to participate in an investigation. All Loss Prevention investigations are confidential. Please do not discuss actions or details with anyone other than the Loss Prevention Department. This will jeopardize the investigation and prolong a loss. Failure to promptly report a potential violation of the law or company policy related to controlled substances and PSE/E listed chemicals can lead to disciplinary action up to and including termination of employment.

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## Reporting Theft and Loss of Controlled Substances, Continued

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### State and Federal Regulations

#### State and Federal Regulations:

As stated in the **Reporting Theft or Loss of Controlled Substances/PSE/E Listed Chemicals Policy (ROPP – 0064)**, Federal regulations require that thefts and significant losses of controlled substances or PSE/E listed chemicals be reported to the DEA.



The DEA must receive initial notification of the theft or loss of controlled substances within **24 hours of discovery of the theft or loss**. Therefore, it is important that all CVS Health colleagues immediately report any suspected theft or loss of a controlled substance to the Pharmacist on Duty, who is responsible for filing the Initial Notification within 24 hours of confirmed loss.

#### What must be reported?

#### All CVS Health colleagues must report instances where you suspect:

- That there may have been a theft of controlled substances or other prescription medications.
- Unauthorized access to or any breach of security regarding controlled substances.
- That there has been an unexplained loss of controlled substances or PSE/E listed chemicals, which might include: a loss of any amount of a controlled substance or PSE/E listed chemicals, a pattern of losses or any other suspicious circumstances regarding the loss of controlled substances or PSE/E listed chemicals.
- The colleague discovering the theft or loss of a controlled substance or PSE/E listed chemicals should report the matter to the Pharmacist on Duty. If the colleague is not comfortable reporting to the Pharmacist on Duty, he/she may notify the Ethics Line by calling 1-877-CVS-2040 (1-877-287-2040).

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## Reporting Theft and Loss of Controlled Substances, Continued

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### State and Federal Regulations

#### State requirements

- Some state agencies also have specific requirements for the reporting of thefts or losses of controlled substances or PSE/E listed chemicals.
- In some cases, the state agency may have different time requirements for the filing of theft/loss notifications or reports, may require that events other than theft or “significant loss” be reported and may require the use of a specific state reporting form.
- Some states have their own theft/loss reporting requirements, and it is the responsibility of any Pharmacist working in those states to be aware of the specific state requirements.

If a loss is suspected, Pharmacists have **72 hours** to perform their due diligence to confirm the loss.

- This includes but is not limited to searching the waiting bin for misfiled prescription(s), checking for bookkeeping or mathematical errors, checking for misplaced inventory on the shelves and safe, etc.

If the Pharmacist’s due diligence results in a confirmed loss, the **Initial Notification** must be submitted **within 24 hours**.

- When determining the date of loss for the Initial Notification, the date in which the loss was confirmed should be used.
- Since the DEA has not defined what constitutes a “significant” loss, the Pharmacist on Duty must submit an Initial Notification for all losses of Controlled Substances or PSE/E Listed Chemicals. With the exception of known miscounts or confirmed dispensing errors, adjustments to inventory involving clerical errors and breakage or spillage of Controlled Substances (unless required by state law) or PSE/E Listed Chemicals.

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## Reporting Theft and Loss of Controlled Substances, Continued

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### State and Federal Regulations

#### To access the Initial Notification Form:

- From RxConnect, press <Alt F3> to access the Inventory Management Menu.
- Select <Option 8> for Reports.
- Select <Option 11> for "Initial Notification of CS Theft or Loss".
- Complete the survey following all instructions provided with each survey question.
- Data from the IN forms submitted will be automatically routed to the Drug Loss Program Team, DEA field office, the Pharmacy and any State agencies, if required.

The Drug Loss Program team will distribute copies of all Initial Notification forms identifying theft or significant loss to the store via fax, which must be filed in the Drug Loss Reporting Forms folder of the Regulatory Records box.

- DO NOT PRINT SCREEN or FAX the electronic Initial Notification form at store level. The form is automatically routed to the applicable agencies. The Drug Loss Program team is responsible for distributing the Initial Notification form to the stores, if required, for record keeping purposes.
- A member of the Drug Loss Program team will enter the information from the Initial Notification Form into the Archer Drug Loss Program Database ("Archer DLP").
- Pharmacists must also notify their Pharmacy Supervisor within 24 hours of any theft or potential loss involving controlled substances.
- In the case of a robbery, the Pharmacist on Duty is responsible for contacting the police department to notify them of the situation.

#### Thefts of controlled substances or PSE/E Listed Chemicals:

- Report all thefts and suspected thefts, regardless of the quantity involved.

For example:

- If the Pharmacy is the victim of colleague theft, armed robbery, burglary, "snatch and grab" or other similar incident where controlled substances or listed chemicals are taken.
- If a colleague is a knowing participant in prescription fraud activity, this qualifies as colleague theft.

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## Reporting Theft and Loss of Controlled Substances, Continued

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### State and Federal Regulations

An immediate e-mail notification will be sent upon entering the Initial Notification into Archer DLP to the District Leader/Pharmacy Supervisor and Asset Protection listed on the form.

Once the District Leader/Pharmacy Supervisor receives the e-mail notification, they must sign into the Archer DLP to review the details of the Initial Notification.

**Note:** If you are not familiar with the Archer DLP please refer to course #820001

#### **“Significant” losses of controlled substances or PSE/E Listed Chemicals:**

- The DEA has not defined “significant,” therefore, the Drug Loss Program team will make the determination, with the assistance of Legal, as to whether a loss qualifies as “significant.” It is the responsibility of the Pharmacy Supervisor to provide the pertinent information required in the Archer database.
- Miscounts or adjustments to inventory involving clerical errors (i.e., incorrect transcription of quantity on invoice or inventory results in a discrepancy) will not be reported to the DEA as a significant loss.
- Note that some states impose different reporting requirements and require the reporting of events other than thefts or significant losses.

Once reported to the Field Leader, they must:

- Confirm that the Initial Notification form was submitted to the appropriate regulatory agencies.
- Coordinate with Loss Prevention to initiate an investigation of the incident.
- If the incident is a theft, it must also be reported to local law enforcement.
- Upon completion of the investigation, complete the 106 fields in the Archer DLP so that the Drug Loss Program team can submit the DEA 106 Form or a Letter of Conclusion.
- Direct questions regarding loss reporting to [Drug\\_Loss\\_Program@CVSCaremark.com](mailto:Drug_Loss_Program@CVSCaremark.com).

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## Reporting Theft and Loss of Controlled Substances, Continued

CS PSE-E  
CFRx IN Job  
Aid



Any pharmacist encountering a suspected loss of **ANY CONTROLLED SUBSTANCE/ PSE-E LISTED CHEMICAL** (regardless of quantity) has up to **72 hours** to perform his/her due diligence to confirm the loss.



Best practices include, but are not limited to:

- ✓ Search all waiting bin areas for misfiled prescription(s)
- ✓ Check for record keeping issues
- ✓ Run a drug usage report for drug(s) in question
- ✓ Check for misplaced inventory on the shelves and safe, etc.



- **ALL thefts or in-transit losses of Controlled Substances/PSE-E Listed Chemical product must be reported immediately and are not subject to the 72 hour due diligence time period**
- **In case of theft/robbery, the Pharmacist-on-duty must also contact the local police**



If the Pharmacist's due diligence results in a **confirmed loss of any amount**, the **Initial Notification "IN"** must be submitted

**within 24 hours of confirmed loss**



The Pharmacist reporting a confirmed loss must submit an **Initial Notification of Controlled Substance/PSE-E LC Theft/Loss "IN"** by following these steps:

In RxConnect:

- Press <Alt F3> to access the **Inventory Management Menu**
- Under the **Maintenance Menu**, Select <Option 8> for **Reports**
- Select <Option 11> for **"Initial Notification of CS Theft or Loss"**
- Complete the survey following all instructions provided with each survey question
- Upon survey submission, data will be sent automatically to the Drug Loss Program Team, DEA field office, the pharmacy, and any State agencies if required.
  - The Pharmacy will receive a copy **via fax** of all INs that have been sent to the DEA, which must be filed in the Drug Loss Reporting Forms folder of the Regulatory Records box



**DO NOT print or fax the Initial Notification form at store level**



Immediately contact your District Leader/Pharmacy Supervisor to notify them of the confirmed loss

### Consequences

Failure by the Pharmacist to report thefts or losses in a timely manner can result in serious consequences for the company, including monetary penalties and other sanctions. Failure by a colleague to immediately report a potential theft or loss of a controlled substance, or a security breach regarding controlled substances can result in disciplinary action, up to and including termination of employment.

District Leaders/Pharmacy Supervisors and Accounts Payable will promptly investigate any incident involving the theft or loss of controlled substances or listed chemicals. Any colleague involved in stealing or diverting controlled substances, listed chemicals or other drugs will be terminated. Information about the incident will also be turned over to law enforcement and state authorities, including State Boards of Pharmacy.










## Store Visits by DEA and Federal Agencies

When your facility receives a visit from the Drug Enforcement Administration (“DEA”) or other Federal agency (FBI, Attorney General, and Office of Inspector General), It is important to follow the process outlined below. Failure to report a regulatory visit or follow proper protocol could result in disciplinary action, up to and including termination.



RxNet → Compliance → Legal and Regulatory → Controlled Substances  
/ Recordkeeping → Controlled Substance Resources

DEA Audit/Visit- Pharmacist Accountability and Procedures	
	<b>1 Verify the DEA Investigator’s credentials</b> Prior to allowing anyone into the Pharmacy, request the Investigator’s identification and business card and make a copy.
	<b>2 Immediately call your District Leader</b> or other member of the field team (e.g. RD or DVP).
	<b>3 Providing documents</b> in accordance with CVS policies. <b>Only provide records requested.</b> The majority of these documents are housed in your regulatory box {e.g. prescriptions, patient profiles, inventory records (DEA 222 forms, biennial inventory, invoices, distribution records), Power of Attorney, DEA 106, DEA 41, DEA registration certificate, self-certification certificate and logbook (or electronic equivalent) and signature logs}. <ul style="list-style-type: none"> <li>• <b>Providing PHI.</b> If the Investigator wishes to record, take originals, or make copies of Protected Health Information (PHI), fax the Regulatory/Law Enforcement Agency PHI Form to the Privacy Office at 401-216-3897. The Pharmacy does not have to call the Privacy Office prior to release.</li> <li>• <b>Make copies of documents taken by the agency and request receipts</b> <ul style="list-style-type: none"> <li>○ Write on the copy “Copy – Original retained by &lt;Agency Name&gt;.”</li> <li>○ Place the copy in the same location as the original.</li> </ul> </li> <li>• <b>Counts of controlled substances.</b> Document and retain the drug names, date and time the Investigator took the count.               <ul style="list-style-type: none"> <li>○ Document the starting point (i.e. biennial count) used for their reconciliation.</li> </ul> </li> </ul>
	<b>4 Fax subpoenas/administrative warrants immediately to: Privacy Office (401) 765-9304.</b>
	<b>5 Investigator questions about Company practices/procedures.</b> The DEA cannot require colleagues to answer questions or participate in an interview during an inspection and it is your choice to respond to DEA questions. <ul style="list-style-type: none"> <li>• Colleagues generally are not required to participate in interviews during DEA inspections.</li> <li>• If you would like legal counsel present for DEA questioning, if you decide to answer questions regarding practices/procedures, you may request immediate legal counsel by contacting your District Leader.</li> <li>• You may ask DEA to wait for legal counsel to be arranged before participating in the interview.</li> <li>• If you do not know the answer to a question, it is appropriate to respond, “I do not know.”</li> </ul>
	<b>6 Make notes about any conversation, documents reviewed,</b> unfinished business/unresolved questions, etc.
	<b>7 Record the occurrence</b> in the “Report Regulatory Audits” Tracker on Spark located under the Applications link directly after the visit concludes, by no later than the end of day.

## Next Steps

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You have now completed the training portion of this course.

To receive credit, you must score 100% on the online assessment via LEARNet. You may utilize this guide to assist you.

